IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-JLH
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50(B)

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'080 patent	U.S. Patent No. 11,541,080
'309 patent	U.S. Patent No. 10,675,309
Bold and italicized	Emphasis added unless indicated otherwise
Borody patents	U.S. Patent Nos. 10,675,309 and 11,541,080
Borody PCT application	PCT/AU2011/00987
CDI	*Clostridium difficile* infection
Ferring	Ferring Pharmaceuticals, Inc. and Rebiotix Inc.
Ferring Pharma	Ferring Pharmaceuticals, Inc.
Finch	Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC
Finch/UMN	Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., Finch Therapeutics Holdings, LLC, and The Regents of the University of Minnesota
FMT	Fecal microbiota transplantation
Hamilton 2012	Hamilton et al., *Standardized Frozen Preparation for Transplantation of Fecal Microbiota for Recurrent Clostridium difficile Infection*, AM. J. GASTROENTEROLOGY. 1-12 (2012)
Hlavka '283 provisional	U.S. Provisional Application No. 61/337,283
Hlavka '184 provisional	U.S. Provisional Application No. 61/351,184
Hlavka or Hlavka PCT application	WO 2011/094027 A1
Hlavka applications	U.S. Provisional Application No. 61/337,283, U.S. Provisional Application No. 61/351,184 and WO 2011/094027 A1
JMOL	Judgment as a matter of law
JTX-___, PTX-___, or TX-____	Refers to exhibits admitted during jury trial held in the above-captioned matter

patents in suit	U.S. Patent Nos. 10,251,914, 10,675,309 and 11,541,080
Markush group limitation	"a fecal donor's intestinal microbiota comprising at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae"
POSA	Person of ordinary skill in the art
PTO	United States Patent and Trademark Office
rCDI	recurrent *Clostridium difficile* infection
Rebiotix	Rebiotix Inc.
relative abundance limitation	"wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10%"
Tr.	Trial transcript
UMN	The Regents of the University of Minnesota
UMN patent	U.S. Patent No. 10,251,914

I. INTRODUCTION

Pursuant to Fed. R. Civ. P. 50(b), Ferring renews its motion for JMOL, Tr. at 596:13-599:13, on six separate grounds.

First, the Court should grant JMOL of invalidity of the sole asserted claim of the UMN patent—claim 7—based on lack of written description. No reasonable jury could have found from the evidence presented at trial that the inventors were in possession of the subject matter claimed. Claim 7 is directed to a broad functional genus that requires six of ten classes of bacteria to be present in the donor's fecal sample that, when administered to a patient in need thereof, results in a 10% reduction of the relative abundance of one or members of the phylum Proteobacteria. The specification has at best one example with taxonomic data from a single donor and single patient that no witness could interpret. This is insufficient as a matter of law, and Finch/UMN's attempt to cure the deficiencies through a multistep inherency theory is unsupported by the specification and woefully deficient for multiple reasons.

Second, the Court should grant JMOL of noninfringement of claim 7 of the UMN patent. No reasonable jury could have found that Ferring has the specific intent to encourage healthcare providers to administer REBYOTA to decrease the relative abundance of one or more members of the phylum Proteobacteria by at least 10%. The Prescribing Information for REBYOTA is devoid of any mention of relative abundance or Proteobacteria. Further, no reasonable jury could have found that there are no substantial noninfringing uses, as more than 15% of patients treated with REBYOTA in Ferring's Phase III clinical study did not meet the relative abundance limitation. The record thus lacks substantial evidence to support the jury's verdict of inducement and contributory infringement.

Third, the Court should grant JMOL of invalidity of claim 2 of the '080 patent and claim 16 of the '309 patent based on obviousness in view of Hlavka and the knowledge of a POSA; to

find otherwise would be inconsistent with the jury's findings of obviousness of claim 9 of the '080 patent and claim 21 of the '309 patent, respectively.

Fourth, the Court should grant JMOL of noninfringement of claims 16 and 21 of the '309 patent. The record lacks substantial evidence that Ferring's REBYOTA product is "in an amount effective for treating recurrence of *C. difficile* infection," as the Prescribing Information for REBYOTA explicitly states that REBYOTA is not indicated for ***treatment*** of CDI; rather, it is indicated for the ***prevention*** of recurrence of CDI and the intrinsic evidence recognizes a distinction between these terms.

Fifth, the Court should grant JMOL of no willful infringement of the Borody patents and the UMN patent. Finch/UMN relies on evidence that cannot demonstrate willful infringement because, among other issues, it predates the issuance of the patents in suit. Further, to the extent Finch/UMN intends to rely on supposed copying of UMN documents to support its claims for willful infringement, the evidence shows that Ferring did not copy anything and, in fact, that the method of manufacturing REBYOTA differs significantly from the methods described in the materials that Rebiotix is accused of copying.

Sixth, it would be legal error to allow the jury's award of an upfront payment of $25M to stand because Finch/UMN's damages expert, James Malackowski, analysis was deficient. Thus, Ferring seeks JMOL that the jury's damages award is unsupported in this regard, or in the alternative, remittitur of the damages award. Additionally, to the extent that the Court grants any of Ferring's co-pending motions and finds either the Borody patents or the UMN patent invalid or not infringed, then the entire damages award (whatever the Court allows to stand) should be reduced to apportion for the respective values of the Borody patents and UMN patent.

II. LEGAL STANDARD FOR JMOL

JMOL is appropriate if "the court finds that a reasonable jury would not have a legally

sufficient evidentiary basis to find for [a] party" on an issue. FED. R. CIV. P. 50(a)(l). "To prevail on a renewed motion for JMOL following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.,* 155 F.3d 1344, 1348 (Fed. Cir. 1998) (alterations in original) (citation omitted); *see* FED. R. CIV. P. 50(b). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 888, 893 (Fed. Cir. 1984). Courts "must scrutinize the evidence carefully to ensure that th[is] 'substantial evidence' standard is satisfied." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1336 (Fed. Cir. 2009).

For damages, the Court should grant remittitur where the award "is clearly unsupported and/or excessive." *Cortez v. Trans Union, LLC*, 617 F.3d 688, 715-16 (3d Cir. 2010).

III. ARGUMENT

A. The Court should grant JMOL that claim 7 of the UMN patent is invalid for lacking written description.

There is no substantial evidence to conclude that claim 7 of the UMN patent is adequately described. A patent's specification "shall contain a written description of the invention," 35 U.S.C. § 112 ¶ 1.1, and "the hallmark of written description is disclosure." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). A specification adequately describes an invention only when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* at 1351. "Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. . . . Requiring a written description of the invention

limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public." *Id.* at 1353. Thus, "[a] 'mere wish or plan' for obtaining the claimed invention is not adequate written description." *Centocor Ortho Biotech, Inc. v. Abbott Labs*., 636 F.3d 1341, 1348 (Fed. Cir. 2011).

Additionally, although written description is a question of fact for the jury, the Federal Circuit has recognized repeatedly that enforcement of the written description requirement is particularly well suited for JMOL due to lay juries' difficulties in interpreting the correct legal standards. *See, e.g., Juno Therapeutics, Inc. v. Kite Pharma, Inc*., 10 F.4th 1330, 1336 (Fed. Cir. 2021) (reversing denial of JMOL on written description); *Idenix Pharms. LLC v. Gilead Scis. Inc*., 941 F.3d 1149, 1165 (Fed. Cir. 2019) (reversing denial of JMOL on written description); *Novozymes A/S v. DuPont Nutrition Bioscis. APS*, 723 F.3d 1336, 1348 n.5, 1351 (Fed. Cir. 2013) (recognizing that prior cases approved of examining written description through JMOL and affirming JMOL of no written description); *Centocor*, 636 F.3d at 1344 (reversing denial of JMOL on written description); *Ariad*, 598 F.3d at 1358 (reversing denial of JMOL on written description).

Asserted claim 7 of the UMN patent, which depends from unasserted claim 4, is directed to a broad, functionally defined genus:

> Claim 4. A method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof, the method comprising:
>
> administering to said patient an effective amount of a pharmaceutical composition comprising a fecal extract or preparation comprising a fecal donor's intestinal microbiota comprising at least 6 different classes of bacteria selected from the group consisting of [10 different classes of bacteria], wherein said fecal extract or preparation is capable of passing through a 0.5 mm sieve and further comprises a pharmaceutically acceptable carrier,

> wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration of said pharmaceutical composition.
>
> Claim 7. The method of claim 4, wherein said method also increases the fecal microbiota diversity in said patient.

JTX-1 at cl. 4, 7. As written, claim 7 encompasses methods of administering a large, diverse group of pharmaceutical compositions comprising fecal bacteria from at least six of the ten specified classes (the Markush group limitation) to a patient, so that it results in a 10% reduction of one or more members of the phylum Proteobacteria (the relative abundance limitation).

When a patent claims methods of using a functionally defined genus, controlling law requires "the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Wyeth LLC v. AstraZeneca Pharms. LP*, No. 21-1338, 2024 WL 3823006, at *15-16 (D. Del. Aug. 14, 2024) (citing *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014) (quoting *Ariad,* 598 F.3d at 1350)).

Regarding the breadth of claim 7, if it were assumed that each of the ten classes of bacteria identified in claim 7 included only a single species—which indisputably they do not—then claim 7 would cover methods involving compositions having 210 different combinations of bacterial species. Tr. at 841:24-842:8 (Treangen). However, it is ***uncontroverted*** that each of the ten enumerated classes are not limited to only a single species (thus providing additional permutations of bacteria that would actually be present in the gut), and therefore, when you "ground this more in the gut microbiome [where] we know there are multiple species per class, this number skyrockets to in the ***millions***" of combinations. Tr. at 841:24-842:8 (Treangen). Additionally, Ferring's expert in computational biology as it pertains to the gut microbiome, Dr.

Treangen, explained that you cannot predict the taxonomic breakdown (i.e., the presence and relative abundance of bacteria or classes of bacteria) even in a healthy individual because "there isn't a universal healthy gut microbiome. It's variable. And even for healthy individuals, it changes and is variable." Tr. at 845:19-846:7. Given the breadth and unpredictability of the claimed subject matter, there is a high bar for the specification to provide either a representative number of species representing the full scope of the claim or common structural features by which a POSA could identify members of the genus. Neither are present here.

Taxonomic data is needed to assess both the Markush group limitation and the relative abundance limitation of claim 7. JTX-1 at cl. 4, 7. Both parties agree that the only taxonomic data provided anywhere in the UMN patent is in Example 1. Tr. at 152:14-16 (Khoruts), 842:15-23, 858:7-17 (Treangen). Dr. Treangen testified that there is "nothing" in the text of Example 1 to support either of these aspects of claim 7. Tr. at 842:15-843:15. Two figures, Figures 1 and 2, provide graphical representations of the data derived from Example 1 intended to reflect the composition of the donor's fecal sample and the patient's fecal samples before and after administration, but those black-and-white figures are illegible and missing the standard accompanying tables of data that could have enabled the determined of whether the donor sample met the Markush group limitation or the recipient samples met the relative abundance limitation. *See* Tr. at 831:24-832:15 (Hamilton), 843:19-845:18, 846:8-848:25, 856:12-857:16 (Treangen). When a drawing or figure is unreadable, it cannot provide written description support. *Minemyer v. B-Roc Reps., Inc.*, 695 F. Supp. 2d 797, 804-05 (N.D. Ill. 2017).

In addition to the testimony of Dr. Treangen, Dr. Khoruts, one of the inventors of the UMN patent, also admitted that he could not read Figure 1. Tr. at 155:12-23. And Dr. Hamilton, another inventor, admitted that he could not read even an in-color copy of the figures, despite

those figures being more detailed and easier to read than those in the UMN patent. Tr. at 831:18-832:15 (referencing TX-3237). Dr. Khoruts did try to suggest that some information could be gleaned regarding the percentage change of the relative abundance of Proteobacteria in the patient by combining the figures and text of Example 1, but neither he nor anyone else explained how this allegedly translated to the specific percentages of the relative abundance limitation. Tr. at 157:13-158:20. Counsel for Finch/UMN intimated during the cross-examination of Dr. Treangen that Finch/UMN's expert, Dr. Schloss, would explain this position, Tr. at 859:13-860:2, but of course he never did, Tr. at 911:15-21, 9:16:18-25. Moreover, Dr. Khoruts himself admitted that, regarding the changes, "[a]t this time" there is no way "to check whether that's actually what happened" because the underlying data was destroyed. Tr. at 158:13-20. Even accepting Dr. Khoruts's unproven assertion regarding changes to the patient's relative abundance of Proteobacteria at face value, ***no witness*** testified that the taxonomic data in Example 1 (or anywhere else in the patent) demonstrates that the donor sample met the Markush group limitation. Therefore, it is undisputed that there is no taxonomic data regarding this requirement of claim 7 in the patent.

Apparently recognizing the deficiencies in the UMN patent's disclosure, Finch/UMN resorts to an inherency theory. That theory requires three steps/assumptions: (1) the donor's fecal sample must be processed using the "standardized" process described by the inventors in Examples 3 and 4; (2) processing the sample in this way will "always" result in a composition meeting the Markush limitation; and (3) administration of the processed sample to a patient suffering from *C. difficile* will necessarily result in meeting the relative abundance limitation. To that end, Finch's technical expert, Dr. Benson, testified that "[t]he '914 patent is really about trying to standardize the approach for preparation of the FMT material" and required "material

that's processed in a blender and [] filtered through a series of sieves, and that preparation when prepared that way would contain at least 6 of the 20 or so common classes of bacteria that are typically found in the microbiome of healthy subjects," Tr. at 352:12-22, and would result in a 10% decrease in Proteobacteria if administered to a *C. difficile* patient, Tr. at 352:23-353:19. Similarly, Dr. Sadowsky testified that "if you start with a healthy human donor and purify the microorganisms as we instructed, both in the paper and the patent, you will always obtain at least six and usually more [of the classes of bacteria that are commonly found in a healthy gut]" (also referred to by Dr. Sadowsky as "at least six classes of [dominant bacteria in the gut]"), and that if such a composition is administered to a patient, the claimed 10% decrease in Proteobacteria will occur. Tr. at 188:24-189:9, 194:5-24. But neither Dr. Benson nor Dr. Sadowsky provided any proof for these statements, and even if accepted as true, Finch/UMN's attempt to argue inherency fails as a matter of law for a number of reasons.

First, both Drs. Benson and Sadowsky caveated their claims about obtaining at least six classes of bacteria by referencing a "healthy" donor. Tr. at 352:12-22 (Sadowsky), 188:24-189:9 (Khoruts). Claim 7, however, does not require a healthy donor.

Second, neither Dr. Benson nor Dr. Sadowsky testified that the "at least six" classes of bacteria in the donor samples referred to in their respective testimonies were from the ten enumerated classes required by claim 7. Dr. Benson referred to "at least 6 of the 20 or so common classes of bacteria that are typically found in the microbiome of healthy subjects," Tr. at 352:12-22, and Dr. Sadowsky referred generically to common/dominant bacteria in a healthy gut microbiome, Tr. at 188:24-189:9, 194:5-24. For both of these reasons, their testimony, even if accepted as true, fails to establish that the donor samples would contain six of the ten ***claimed*** classes of bacteria.

Third, claim 7 does not require any specific manufacturing process, and instead requires only that the "fecal extract or preparation is capable of passing through a 0.5 mm sieve." *See* JTX-1, cl. 7(4). But Dr. Benson references the use of a "standardize[d]" approach using a blender and a series of sieves to yield a composition containing "at least 6 of the 20 or so common classes of bacteria." Tr. at 352:12-22. Similarly, Dr. Sadowsky referenced "purify[ing] the microorganisms as we instructed, both in the paper and the patent"—i.e., in Hamilton 2012 and in Examples 3 and 4 of the UMN patent—to get the "at least six" classes of bacteria. Tr. at 188:24-189:9. Even if claim 7 did require specific manufacturing steps from the patent, it is undisputed that the composition used in Example 1—the portion of the patent containing taxonomic data—was manufactured the "old-fashioned way," not using the methods described in Example 3 or Hamilton 2012. Tr. at 143:25-144:16, 151:15-18, 161:20-23 (Khoruts). Again, their testimony, even if accepted as true, fails to provide support for the full scope of the claim, and in this case serves to further undercut any alleged relevance of Example 1.

Fourth, the specification of the UMN patent does not disclose or even suggest that the claimed six of ten classes represents a healthy gut or that any combination of at least six of the ten classes would produce desirable results. *See* JTX-1 at 5:19-29, 7:63-8:19. Instead, the specification includes a laundry list of potential taxonomic groupings without any reference to the benefits or drawbacks of any particular groupings, which is not sufficient to show written description. *See* JTX-1 at 5:19-29, 7:63-8:19; *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435, 446 (D. Del. 2021) (Judge Bryson citing multiple Federal Circuit cases to support that "[s]imply presenting a 'laundry list' of compositions that might or might not satisfy the claims is not sufficient" to satisfy written description). Further, there is no support that any combination of at least six of the ten enumerated classes would be desirable, particularly when at

least three of those classes (Alphaproteobacteria, Betaproteobacteria, and Gammaproteobacteria) are from the phylum Proteobacteria, the very bacteria that the method of claim 7 seeks to reduce. *See* JTX-1 at cl. 7. The specification provides no guidance on this issue nor does the testimony of Drs. Khoruts or Sadowsky.

Fifth, the specification does not indicate that a decrease in the relative abundance of Proteobacteria of at least 10% would affect the course of *C. difficile* infection let alone be associated with a therapeutic effect. Instead, the UMN patent includes a laundry list of possible reductions in Proteobacteria, without indicating how they may be achieved or what outcomes may be associated with such reductions. *See* JTX-1 at 15:42-52; *Lipocine*, 541 F.Supp.3d at 446. Nowhere in the specification does it teach that a particular reduction in the relative abundance of Proteobacteria will produce a specific result, nor did Drs. Khoruts or Sadowsky testify that such information is or would have been known.

Sixth, even ignoring all of these other deficiencies, there was ***no*** testimony at trial that it was generally known in the art ***at the time of the invention*** that using the specific manufacturing method described in the UMN patent (which is not required in claim 7) to prepare a sample from a healthy donor (which also is not required by the claim) would result in a composition with at least six classes of bacteria commonly found in a healthy gut microbiome (which may not result in six of the ten specific classes recited in the claim), and that administering that composition to a patient allegedly would necessarily result in at least a 10% reduction in one or more members of the phylum Proteobacteria (despite testimony that this does not always occur, Tr. at 359:16-363:4 (Benson)). And such information certainly is not included in the specification. The only portion of the specification providing actual taxonomic data is Example 1, and the figures containing that data are illegible. And since written description must be addressed within the four

corners of the patent, there is no evidence that a POSA would understand the inventors to have been in possession of the claimed invention. *See Ariad*, 598 F.3d at 1351 (explaining that the written description inquiry is restricted to the "four corners of the specification[.]")

Additionally, even if the figures of Example 1 were not illegible, Example 1 is limited to one donor and one patient, Tr. at 150:13-151:3, 154:5-11 (Khoruts), and both parties agree that an N of 1 is not science, Tr. at 155:6-11 (Khoruts), 850:8-851:7 (Treangen). And as explained by Dr. Treangen, when you consider the high variability in the human microbiome, a POSA cannot extrapolate those findings of a single individual patient to an entire population. Tr. at 850:8-851:7; *see also* Tr. at 845:22-850:7. There is no dispute that such a conclusion would not be scientifically sound. Tr. at 850:8-851:7 (Treangen). Thus, even if a POSA could read Figures 1 and 2, Example 1 is legally insufficient to support the broad functional scope of claim 7. *See Ariad*, 598 F.3d at 1358.

Finally, Example 4 cannot be relied on to expand the taxonomic data from Example 1. Dr. Khoruts tried to suggest that Example 4 expands data past 1 patient to 43 patients. *See* Tr. at 103:25-104:22, 171:20-172:24. However, there is no taxonomic data in Example 4. Tr. at 849:1-850:7 (Treangen). Moreover, the text of Example 4 itself identifies "***a number of limitations*** to this study," including "[t]he complexity of the donor material preparations, technical inability to culture most of the contained microbial constituents by classic laboratory techniques, and ***our ignorance as to the identity of species that are therapeutically most important precluded simple tests of donor material prior to FMT that could predict its efficacy***." JTX-1 at 28:31-55. In fact, the inventors stated that they were "currently working to characterize the microbial composition of donor material and recipients' fecal samples collected over time." JTX-1 at 28:31-55. "Although the content varies, the threshold [for written description] in all cases requires a

transition from theory to practice, from basic science to its application, from research plan to demonstrated utility." *Ariad*, 598 F.3d at 1359. Here, the UMN inventors can only be attributed a research plan that had not yet transitioned to practice, and thus is not a patentable invention.

For all the above reasons, the trial evidence, viewed under the proper standards, permitted no other conclusion than that claim 7 of the UMN patent is invalid for lack of written description by clear and convincing evidence. Therefore, the Court should grant JMOL and find claim 7 of the UMN patent invalid.

B. The Court should grant JMOL that claim 7 of the UMN patent is not infringed.

Finch/UMN concedes that Ferring does not directly infringe claim 7 of the UMN patent, and no reasonable jury could have found indirect infringement of the elements: "[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof" and "wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10%." JTX-1, cls. 4, 7.

1. There is no substantial evidence that Ferring induces infringement.

"It is well-established that 'mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.'" *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.,* 785 F.3d 625, 631 (Fed. Cir. 2015) (citation omitted). Finch/UMN failed to present substantial evidence that Ferring specifically intended to encourage healthcare providers to administer REBYOTA so as to satisfy the relative abundance limitation.

At trial, the focus of Finch/UMN's presentation of evidence was directed towards equating the indicated use of REBYOTA for the ***prevention*** of recurrent CDI following antibiotic treatment, *see* PTX-117.1, with using REBYOTA to ***treat*** the recurrence of CDI, *see,*

e.g., Tr. at 321:11-328:9 (Stollman), 379:3-13 (Benson); PTX-1632; PTX-604; PTX-325; PTX-376; PTX-608. But Finch/UMN failed to adduce any evidence that Ferring encourages healthcare providers to perform "[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria to a patient in need thereof." While Finch/UMN's expert gastroenterologist, Dr. Stollman, testified that Ferring encouraged healthcare providers to use REBYOTA to treat the recurrence of CDI, Tr. at 316:3-18, 318:8-16, 328:6-9, he provided no testimony regarding the relative abundance limitation, *see generally* Tr. at 321:11-328:9. Similarly, Finch/UMN's expert Dr. Benson, in providing the ultimate opinion on infringement of claim 7, simply relied on Dr. Stollman's opinion that Ferring "instructs and encourages healthcare providers to administer REBYOTA to treat recurrent CDI." Tr. at 379:3-13.

Similarly, Finch/UMN has argued that Ferring has the specific intent to induce infringement by "providing a label with instructions for administration which, if followed, would infringe claim 7." D.I. 475 at 9. That is legally insufficient. "The pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010); *see also Vita–Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n. 2 (Fed. Cir. 2009) ("The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent."). Here, the Prescribing Information for REBYOTA is devoid of any mention of reducing the relative abundance of Proteobacteria or, more generally, the specific bacterial composition of REBYOTA. In fact, the Prescribing Information specifically states that "[t]he mechanism of action of REBYOTA has not been established." PTX-117.8. There is simply no information in the Prescribing Information from

which a reasonable jury could adduce Ferring's specific intent to induce infringement of the relative abundance limitation of claim 7 of the UMN patent. *See Biogen Inc. v. Sandoz Inc.*, No. 22-1190-GBW, 2023 WL 7130655, at *9 (D. Del. June 29, 2023) (finding that a label "fail[ing] to recite each and every claim limitation . . . does not induce infringement because it does not encourage, recommend, or promote an infringing use").

Finally, to the extent that Finch/UMN argues that alleged copying supports a finding that Ferring had knowledge of and intent to cause the infringing acts, this argument misses the mark for the same reasons explained in refuting Finch/UMN's allegations of willful infringement. *See* § III.E.2, *infra*.

There was no evidence, much less substantial evidence, presented to the jury regarding Ferring's specific intent to induce infringement of the relative abundance limitation.

2. There is no substantial evidence that Ferring contributorily infringes.

Similarly, no reasonable jury could have found Ferring liable for contributory infringement with respect to REBYOTA. To prove contributory infringement, Finch/UMN was required to show that REBYOTA has "no substantial non-infringing uses." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1362 (Fed. Cir. 2012); 35 U.S.C. § 271(c). Dr. Stollman, in an entirely conclusory fashion, said 11 words on the matter of substantial non-infringing uses: "Q: Now, does REBYOTA have any substantial non-infringing uses? A: It does not. Q: Why not? A: There is no other use for this product." Tr. at 327:20-24. Dr. Stollman did not address whether REBYOTA can be administered for uses other than reducing the relative abundance of one or more members of the phylum Proteobacteria, as required by claim 7, and, as with inducement, Dr. Benson simply relied on Dr. Stollman's opinion in providing his ultimate opinion on contributory infringement, Tr. at 385:19-25. This conclusory testimony is not substantial evidence capable of satisfying Finch/UMN's burden to prove infringement. *Yoon Ja Kim v.*

ConAgra Foods, Inc., 465 F.3d 1312, 1320 (Fed. Cir. 2006) (affirming JMOL of noninfringement where "conclusory [expert] testimony" was the basis for infringement).

Yet the evidence was undisputed that REBYOTA does in fact have substantial non-infringing uses, i.e., uses that are "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. Finch/UMN's own experts admitted that Ferring's Phase 3 dataset reflects that only 84.75% of patients with recurrent CDI who received REBYOTA experienced at least a 10% relative reduction in Proteobacteria. PTX-136.66; Tr. at 359:16-363:4 (Benson), 506:10-507:1 (Malackowski). Therefore, administration of REBYOTA does not meet the relative abundance limitation in more than 15% of patients, which confirms that there are substantial noninfringing uses for REBYOTA. *See Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 685 (D. Del 2016), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017) ("Because it is undisputed that approximately 20% of dronedarone users do not have one of the claimed cardiovascular risk factors, I find that there are substantial non-infringing uses for Defendants' proposed ANDA product. Accordingly, I conclude that there is no contributory infringement."); *Grunenthal GmBH v. Alkem Lab'ys Ltd*., 919 F.3d 1333, 1340-41 (Fed. Cir. 2019) (finding after trial that a use pattern of a drug the plaintiffs' expert conceded would occur less than 5% of the time was a sufficiently substantial use to defeat a contributory infringement claim). Therefore, no reasonable jury could find claim 7 of the UMN patent contributorily infringed by sales of REBYOTA.

C. The Court should grant JMOL that claim 2 of the '080 and claim 16 the '309 patent are invalid as obvious.

There is no substantial evidence to support the jury's finding that claim 2 of the '080 patent and claim 16 of the '309 patent were not invalid as obvious. "Obviousness is a question of law based on underlying findings of fact." *See Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237,

1246 (Fed. Cir. 2010) (granting judgment as a matter of law of obviousness). The Supreme Court has made clear that "[t]he ultimate judgment of obviousness is a legal determination," and thus is reviewed *de novo* on appeal. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007); *Bos. Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 990 (Fed. Cir. 2009) ("[The Federal Circuit] review[s] the jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence") (citation omitted). Where "the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors," JMOL is appropriate. *Wyers*, 616 F.3d at 1239 (quoting *KSR*, 550 U.S. at 427); *see also ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1362 (Fed. Cir. 2015) ("[E]ven assuming that the jury correctly resolved pertinent factual disputes in favor of [the plaintiff], the prior art still renders the claims of the [asserted] patent obvious as a matter of law."); *Bos. Sci. Scimed*, 554 F.3d at 990 ("When we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination.") (reversing denial of JMOL as to obviousness). The jury's findings of fact regarding these issues—illuminated by its finding claim 9 of the '080 patent and claim 21 of the '309 patent obvious—mandate similar findings regarding the remaining claims of the Borody patents.

1. Claim 2 of the '080 patent is obvious in view of Hlavka and the knowledge of a POSA.

It is undisputed that the Hlavka applications are prior art to the Borody patents; the Hlavka '283 provisional (TX-3150), Hlavka '184 provisional (TX-3164), and Hlavka PCT applications (TX-3330) were filed on February 1, 2010, June 3, 2010, and February 1, 2011, respectively. Tr. at 870:13-18 (Britton). The earliest priority date of the Borody patents is to a

provisional application filed on March 2, 2011—one month after the Hlavka PCT application. Tr. at 871:2-8 (Britton).

Claim 2 of the '080 patent depends from claim 1, which together state:

> Claim 1. An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a sealed container, a tubing equipment, and a pharmaceutical composition within the sealed container, wherein the pharmaceutical composition is formulated for enema delivery from the sealed container via the tubing equipment, wherein the pharmaceutical composition comprises a microbiota suspension comprising a ***cryoprotectant*** and viable uncultured non-pathogenic fecal bacteria from a stool of a human donor that has been prescreened for infectious agents, and ***wherein the pharmaceutical composition is stable during long term storage of the sealed container when frozen.***
>
> Claim 2. The enema delivery system of claim 1, wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen or exposed to air.

JTX-6, cls. 1, 2. Claim 9, which also depends from claim 1, was found obvious by the jury in view of Hlavka and the knowledge of a POSA. JTX-6, cl. 9; Tr. at 1255:22-1256:3. Thus, independent claim 1 of the '080 patent also is invalid as obvious in view of Hlavka and the knowledge of a POSA. *Callaway Golf Co. v. Acushnet Co.,* 576 F.3d 1331, 1344 (Fed. Cir. 2009) ("A broader independent claim cannot be nonobvious where a dependent claim stemming from that independent claim is invalid for obviousness."). Therefore, the jury's determination of nonobviousness of claim 2, Tr. at 1255:22-1256:3, rests on the supposed novelty of the added limitation that "the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen or exposed to air," JTX-6, cl. 2. However, considering the findings regarding claim 1, no reasonable jury could have reached this conclusion when considering the teachings of Hlavka, the unrebutted testimony of Ferring's expert Dr. Britton, Tr. at 916:18-22 (Finch/UMN indicating that rebuttal invalidity witnesses

would not be called), and the admissions of Finch/UMN's own witnesses.

First, claim 1 requires that "the pharmaceutical composition is ***stable*** during long term storage of the ***sealed*** container when ***frozen***," JTX-6, cl. 1, which the jury already found is obvious in view of Hlavka and the knowledge of a POSA, Tr. at 1255:22-1256:3. Thus, claim 2's requirement that "the system ***protects*** the fecal bacteria within the pharmaceutical composition from destruction when the ***sealed*** container is ***frozen***," JTX 6, cl. 2, also is obvious.

Second, Dr. Britton provided unrebutted testimony that Hlavka teaches storing the sample in "a sealed container," as required by claim 2 (and claim 1). TX-3330 at 8:6-8 ("Accordingly, the processing can include placement into a sterile delivery container…"); Tr. at 883:4-9 ("Hlavka says…that this is actually placed into a sterile delivery container, which, by nature, has to be sealed if it's sterile.").

Third, Dr. Britton testified that Hlavka explicitly teaches the addition of a cryoprotectant, which serves to "protect the composition during freezing." TX-3330 at 40:1-3 ("wherein the processing each of the received donor fecal samples includes homogenizing, filtering, and ***adding a cryoprotectant*** to each of the donor fecal samples"); Tr. at 883:4-6 ("Hlavka says adding a cryoprotectant and that would be for the express purpose of protecting it during freezing."). Finch/UMN's witnesses agreed that the addition of cryoprotectants serves to stabilize the samples during freezing. Tr. at 353:20-354:8 (Dr. Benson testifying that "[the Borody patents are] about putting cryoprotectants into that microbiome sample or to the stool sample and antioxidants into the stool sample to stabilize it during freezing and to keep - - help keep oxygen away from it."); Tr. at 196:14-197:7 (Dr. Sadowsky testifying to communications with Hlavka about cryoprotectants to preserve microorganisms during freezing and thawing). Thus, no reasonable jury could have found the limitation of claim 2 to "protect[] the fecal

bacteria within the pharmaceutical composition from destruction when the sealed container is frozen" nonobvious in light of Hlavka's disclosure to add a cryoprotectant.

Hlavka's teaching regarding the use of a cryoprotectant to protect the composition during freezing is determinative. Where a single claim covers plural alternative embodiments, such as claim 2's requirement that "the system protects the fecal bacteria . . . when the sealed container is frozen ***or*** exposed to air," the claim is obvious if the prior art demonstrates the obviousness of any one of them. *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 343 F. Supp. 3d 823, 845-46 (N.D. Ill. 2018), *aff'd*, 946 F.3d 1322 (Fed. Cir. 2020) (collecting cases). Thus, the Court need go no further to grant JMOL of obviousness of claim 2. Nevertheless for the sake of completeness, the alternative embodiment requiring "protect[ing] the fecal bacteria . . . when the sealed container . . . is exposed to air" is obvious as well. In finding claim 9 obvious, the jury necessarily found it obvious to add an antioxidant to the composition. Tr. at 1255:22-1256:3; JTX-6, cl. 9 ("wherein the pharmaceutical composition further comprises antioxidants"). And Finch/UMN's experts admitted that antioxidants are meant to protect against exposure to air. Tr. at 354:1-4 (Benson) ("[The Finch patents are] about putting cryoprotectants into that microbiome sample or to the stool sample and antioxidants into the stool sample to stabilize it during freezing and to keep - - help keep oxygen away from it."); *see generally* Tr. 333:2-340:18 (Park).

Thus, given the unrebutted expert testimony of Dr. Britton, the explicit teaching of Hlavka to add a cryoprotectant, the implicit finding by the jury that it would be obvious to add an antioxidant (claim 9), and the admitted function of cryoprotectants and antioxidants, claim 2 is obvious in view of Hlavka and the knowledge of a POSA as a matter of law.

2. Claim 16 of the '309 patent is obvious in view of Hlavka and the knowledge of a POSA.

Claim 16 of the '309 patent depends from claim 12, which together state:

> Claim 12. An enema product configured for transporting to a remote facility, the enema product comprising flexible tubing, a sealed bag, and a pharmaceutical composition within the bag, wherein the pharmaceutical composition is formulated for enema delivery from the bag, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a suspension of viable non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the fecal bacteria are separated from rough particulate matter and are not cultured, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of C. difficile infection.
>
> Claim 16. The enema product of claim 12, wherein the cryoprotectant comprises polyethylene glycol.

JTX-4, cls. 12, 16. The jury found claim 21 of the '309 patent, which also depends on claim 12, obvious in view of Hlavka and the knowledge of a POSA. JTX-4, cl. 21; Tr. at 1255:22-1256:3. Therefore, claim 12 also is obvious in view of Hlavka and the knowledge of a POSA. *Callaway Golf*, 576 F.3d at 1344. No reasonable jury could have found claim 16 of the '309 patent—which restricts the cryoprotectant include polyethylene glycol (PEG)—nonobvious over Hlavka and the knowledge of a POSA, for reasons discussed below.

It is undisputed that Hlavka discloses glycol as a cryoprotectant. TX-3330 at 18:27-28 ("In Example 54, the adding the cryoprotectant of any one or more of Examples 1-53 can optionally include at least one of glycol, glycerol, dimethyl sulfoxide (DMSO), dairy milk, or soy milk."). Further, it is undisputed that polyethylene glycol is a glycol. Tr. at 886:5-887:1, 905:1-6 (Britton admitting); Tr. 341:19-342:18 (Park admitting). In addition, the Supreme Court in *KSR* explained that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 550 U.S. at 402-03. While both parties agreed that there are hundreds of glycols,

Finch/UMN's expert Dr. Park testified that not many are common in pharmaceutical formulations, Tr. 343:25-344:4, and Dr. Britton testified that some glycols can be fatal to humans, Tr. at 899:6-18. Thus, there are a "finite number" of glycols that a POSA would have "good reason to pursue," and here, the disclosure of glycol as a cryoprotectant in Hlavka renders obvious the specific use of PEG. *KSR*, 550 U.S. at 402-03.

A POSA also would have been further motivated to select PEG as a cryoprotectant in Hlavka's enema FMT product because PEG can serve as an antioxidant as well—a characteristic identified by Dr. Park, and an element which the jury already found would have been obvious. TX-3330 at 5:23-25; Tr. at 336:14-25 (Park); Tr. at 896:21-897:2, 909:23-910:15 (Britton).

At trial, Finch/UMN pursued a misleading line of questioning relating to Rebiotix's arguments to the PTO during the prosecution of an unrelated patent regarding a document that is not prior art, and therefore does not demonstrate teaching away. *See generally* Tr. at 900:14-905:6. Specifically, Finch/UMN's counsel pointed Dr. Britton to the following statement made by the Applicant:

> Furthermore, polyethylene glycol is typically used to purge the gut and is available commercially as the active ingredient of some laxatives. Indeed Hamilton only mentions polyethylene glycol in the context of purging the gut, which teaches away from using polyethylene glycol with a microbiota restoration therapy composition. Because of this, it would not be obvious to combine a substance that functions as a laxative to a microbiota restoration therapy composition.

Tr. at 903:23-904:10; PTX-979.535. This was referring to Hamilton 2012, which is not prior art to the '309 patent.

Thus, given the explicit teaching of Hlavka to add a glycol to act as a cryoprotectant, the admissions from Finch/UMN's experts regarding PEG being a glycol, and the finite number of glycols available for use as a cryoprotectant in a pharmaceutical composition, claim 16 is

obvious in view of Hlavka and the knowledge of a POSA as a matter of law.

3. No reasonable jury could have found that any secondary consideration supports the nonobviousness of either claim 2 of the '080 patent or claim 16 of the '309 patent.

Lastly, no reasonable jury could have found any secondary consideration to support the nonobviousness of either claim 2 of the '080 patent or claim 16 of the '309 patent. Finch/UMN has suggested that "the jury was shown extensive evidence of objective indicia with a nexus to the '309 claims, including licensing, commercial success, long-felt need, unexpected results, failure by others (including Hlavka), skepticism, and (extensive) copying by others, which confirm that selecting PEG as the cryoprotectant or using an antioxidant in an FMT formulation packaged as a ready-to-use enema was not an obvious choice." D.I. 475 at 14. However, these arguments are entirely conclusory, and objective indicia must have a nexus to the novel features of the invention. *In re Kao*, 639 F.3d 1057, 1068, 1074 (Fed. Cir. 2011); *Bombardier Recreational Prod. Inc. v. Arctic Cat Inc.*, 785 F. App'x 858, 870-871 (Fed. Cir. 2019). The jury found adding an antioxidant to the enema product and enema delivery system of claim 1 of the '080 patent and claim 12 of the '309 patent, respectively, was obvious. Tr. at 1255:22-1256:3; JTX-6, cls. 1, 9; JTX-4, cls. 12, 21. Therefore, an antioxidant cannot be a novel feature. PEG also is not a novel feature because, by Dr. Park's own admission, PEG is an antioxidant. Tr. at 342:19-20. And lacking a rebuttal case on invalidity, Finch/UMN did not lay a foundation for a nexus with anything else. Therefore, no record evidence shows any purported secondary considerations of nonobviousness that can be tied to a novel feature of the claimed inventions. To find otherwise would lead to inconsistent judgments between the obviousness of (i) claim 9 of the '080 patent and claim 21 of the '309 patent and (ii) claim 2 of the '080 patent and claim 16 of the '309 patent, respectively.

D. The Court should grant JMOL that claims 16 and 21 of the '309 patent are not infringed.

There is no substantial evidence that REBYOTA "is in an amount effective for ***treating*** recurrence of *C. difficile* infection," JTX-4, cl. 12, such that Ferring infringes claims 16 and 21 of the '309 patent. Both the specification of the '309 patent and the prosecution history of an earlier application in its chain recognize a distinction between "treatment" and "prevention". *See, e.g.,* JTX-4 at 1:51-54 ("In alternative embodiments, compositions, devices and methods of the invention are used for the amelioration, stabilization, ***treatment*** and/or ***prevention*** of a disease or a condition."); *see also* JTX-4 at 4:14-17, 4:53-58, 4:58-61, 4:66-5:19, 5:31-47, 5:48-65, 5:66-6:17, 10:40-55, 10:56-65, 16:64-17:9, 23:36-46, 23:50-24:16, 24:17-35 (same); JTX-4.2; PTX-9.79 at cl. 53.

The FDA similarly recognized this distinction in approving REBYOTA. The Prescribing Information for REBYOTA explicitly states that REBYOTA is not indicated for ***treatment*** of CDI; rather, it is indicated for the ***prevention*** of recurrence of CDI:

> **1 INDICATIONS AND USAGE**
>
> REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI.
>
> Limitation of Use:
>
> REBYOTA is not indicated for treatment of CDI.

PTX-117.2. This FDA-approved indication for REBYOTA was based on "a Bayesian analysis of data from a randomized, doubleblind, placebo-controlled, multicenter Phase 3 study (Study 1), which formally integrated treatment success rates from a placebo-controlled Phase 2 study (Study 2)," as described in the Clinical Studies section of the Prescribing Information. PTX-117.9; 21 C.F.R. § 201.57(c)(15).

Ignoring the FDA-approved indication, Dr. Stollman opted to rely on unofficial

statements made by Ferring referring to REBYOTA as a "treatment" of recurrent CDI prior to approval. *See* D.I. 475 at 4.n1 (citing Tr. at 318:17-325:15; PTX-117.9; PTX-118.3; PTX-604; PTX-686.7; PTX-1690.2; PTX-1632 at 1:25:55-1:26:16). No reasonable jury, however, could find that such evidence provides a sufficient basis to prove infringement. The FDA actually analyzed the data underlying the studies referred to in these exhibits and determined that REBYOTA was in fact not effective in treating CDI, but rather was effective only in preventing the recurrence of CDI. PTX-117.1, -.9; 21 C.F.R. § 201.57(c)(2).

E. The Court should grant JMOL of no willfulness.

Willful infringement requires that Ferring both knew of the Borody patents and the UMN patent and had the subjective intent to infringe those patents. *bioMérieux, S.A. v. Hologic, Inc.*, No. 18-cv-21-LPS, 2020 WL 759546, at *11 (D. Del. Feb. 7, 2020); *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987 (Fed. Cir. 2021). Finch/UMN lumps its arguments regarding willfulness of the asserted patents together, D.I. 475 at 11-12, but the jury's finding of willfulness must be considered on a patent-by-patent basis. For the reasons discussed below, the evidence presented at trial is insufficient for a willfulness determination for both the Borody patents and the UMN patent as a matter of law.

1. There is no substantial evidence that Ferring has willfully infringed the Borody patents.

Finch/UMN's purported evidence of willfulness of the Borody patents rests solely on Ferring's (i) knowledge of the Borody PCT application and the '309 patent prior to this litigation and (ii) the indemnification clause in the March 2018 merger agreement between Ferring Pharma and Rebiotix ("Merger Agreement"), PTX-56, which was entered into before either the '309 or '080 patent issued or were even filed, JTX-4, JTX-6. *See* D.I. 475 at 11-12. This evidence is insufficient for a willfulness determination as a matter of law.

a. Ferring's presuit knowledge of the Borody PCT application and the '309 patent alone is not a sufficient basis for a finding of willful infringement.

"To prove willful infringement, a patentee must prove, by a preponderance of the evidence, that an accused infringer took actions, ***with knowledge of the patent***, and with the intent of infringing the patent." *bioMérieux*, 2020 WL 759546, at *11 (emphasis added). Preliminarily, Ferring could not have had presuit knowledge of the '080 patent. This litigation was filed on December 1, 2021, D.I. 1, but the '080 patent did not issue until January 3, 2023, from an application that was filed in May 2022, JTX-6.2. Regarding the '309 patent, while Ferring was aware that it issued on June 2, 2020, "[p]resuit knowledge alone is not a sufficient basis for a finding of willful infringement," *bioMérieux*, 2020 WL 759546, at *11.

b. There is no substantial evidence that the Merger Agreement evidences Ferring's subjective intent to infringe.

Finch/UMN has argued that Ferring's intent to infringe is "demonstrated by its insistence that Rebiotix indemnify Ferring [Pharma] for infringement of the patents-in-suit." D.I. 475 at 12 (citations omitted). Specifically, Finch/UMN relies on section 1.16(h) of the Merger Agreement as evidence that Ferring "knew its design was infringing . . . all of the patents-in-suit in this case." Tr. at 987:7-14; PTX-56.20; *see also* Tr. at 569:23-572:23 (Berman). That section, in part, calls for a reduction in any milestone and/or earnout payment under the Merger Agreement to account for fifty percent of the legal expenses for litigation involving certain identified patents. PTX-56.20 at § 1.16(h)(iii) and (iv), - .96, -.248. However, no reasonable jury could find that the Merger Agreement evidences Ferring's subjective intent to infringe.

First, the Federal Circuit has explained:

> To willfully infringe ***a patent***, the patent must exist and one must have knowledge of it. A "patent pending" notice gives one no knowledge whatsoever. It is not even a guarantee that an application

> has been filed. Filing an application is no guarantee any patent will issue and a very substantial percentage of applications never result in patents. What the scope of claims in patents that do issue will be is something totally unforeseeable.

State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1236 (Fed. Cir. 1985) (emphasis in original); *see also Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990) (noting that there can be no willful infringement before a patent issues). Here, the applications that issued as the '309 and '080 patents were not filed until nineteen months and four years, respectively, after the Merger Agreement was executed. JTX-4.2; JTX-6.2; PTX-56.1. At best, the Merger Agreement shows that Ferring had knowledge of the Borody PCT application to which the '309 and '080 patents claim priority and applications related to the Borody patents, PTX-56.248, not knowledge of the Borody patents themselves. Thus, the Merger Agreement cannot support a finding of willfulness as a matter of law. *Bioverativ Inc. v. CSL Behring LLC*, No. 17-cv-914-RGA, 2020 WL 1332921, at *2 (D. Del. Mar. 23, 2020).

Second, even if the asserted claims of the Borody patents had existed at the time of the Merger Agreement, the indemnification clause would be insufficient to show that Ferring had the subjective belief that REBYOTA would infringe those claims. In general, pre-patent-issuance actions are not relevant to willfulness unless they are "particularly egregious" and show a party's subjective intent to infringe. *Bioverativ*, 2020 WL 1332921, at *2 (collecting cases). Here, rather than demonstrating Ferring's specific intent to infringe, section 1.16(h) is an acknowledgement that Ferring believed Finch/UMN would aggressively seek to enforce any patents that eventually issued—a supposition that is borne out by this litigation and Finch's continued prosecution of patents specifically to cover REBYOTA (e.g., the '080 patent).

In fact, in section 3.9(b) of the Merger Agreement, Rebiotix specifically represented its belief that REBYOTA was not infringing any valid patent:

> To the Company's Knowledge [i.e., Rebiotix's knowledge], there is no Intellectual Property owned by any third party that (i) the Company in good faith believes is valid and enforceable, (ii) is required by the Company to conduct its business as currently conducted and (iii) the Company is not currently authorized to use.

PTX-56.27. This belief is supported by the Ferring Pharma due diligence report, TX-3960, and board briefing notes on that report, PTX-341, that were contemporaneously prepared by Ferring Pharma as part of the due diligence for the merger. The due diligence report, dated December 2017, notes that both Ferring Pharma and Rebiotix had conducted freedom to operate searches as part of the due diligence. TX-3960-75; Tr. at 678:4-14. And the due diligence briefing notes to the Ferring Pharma board, dated March 14, 2018, state that "[o]ne of the competitors in this area [Finch] has taken aggressive positions on building a patent portfolio" and that the "expectation is that they would take a similarly aggressive position to litigate any patents they believed relevant." PTX-341.4. In other words, Ferring Pharma was concerned that Finch would aggressively litigate its patents, and the parties included section 1.16 as a cost sharing mechanism in the face of expected patent litigation by Finch.

c. There is no substantial evidence of Ferring's subjective intent to infringe after the Merger Agreement

Finally, there is no substantial evidence that Ferring's subjective beliefs regarding infringement and invalidity changed after any of the Borody patents issued. *See Bioverativ*, 2020 WL 1332921, at *2 (noting that in general, only post-issuance behavior is relevant to willfulness, unless the actions were particularly egregious). With respect to the evidence that Ferring continued to monitor the patent families identified in the Merger Agreement, Tr. at 288:12-19, 289:3-6, 676:6-12, courts in this District have explained that "competitive intelligence is standard in the pharmaceutical industry" and, without more, cannot rise to the level of willfulness. *Id.* Here, it is undisputed that both Ferring and Finch/UMN were monitoring each

other's development and intellectual property filings. *See, e.g.*, Tr. at 288:12-19, 289:3-6 (Fluet), 676:6-12 (L. Jones) (Ferring competitive intelligence); Tr. at 458:17-461:25 (Burgess), 231:5-16 (Anderson) (Finch competitive intelligence); TX-3814-17, -35, -39 (Finch competitive intelligence); TX-3743 (Finch competitive intelligence); TX-3746 (Finch competitive intelligence). Without more, however, this competitive intelligence is not sufficient to reasonably support a finding of willfulness. *Bioverativ*, 2020 WL 1332921, at *2.

For these reasons, no reasonable jury could find that the Merger Agreement is proof of knowledge or subjective intent to infringe the asserted claims of the Borody patents, which did not exist at the time the Merger Agreement was executed.

2. There is no substantial evidence that Ferring has willfully infringed the UMN patent.

a. The Merger Agreement does not demonstrate knowledge of the UMN patent nor Ferring's subject intent to infringe.

The deficiencies in Finch's proof of willfulness with respect to the Borody patents similarly applies to the UMN patent. Specifically, the UMN patent—like the Borody patents—did not issue until after the Merger Agreement. JTX-1.2; PTX-56.1. Thus, no reasonable jury could find that the Merger Agreement is proof of knowledge or subjective intent to infringe the asserted claims of the UMN. *Gustafson*, 897 F.2d at 510; *see also State Indus.*, 751 F.2d at 1236 (Fed. Cir. 1985). The Merger agreement at best shows that Ferring had knowledge of the parent application and related applications to the UMN patents, but not knowledge of the UMN patent itself, which is required to support a finding of willfulness. *Bayer*, 989 F.3d at 988; *Bioverativ*, 2020 WL 1332921, at *2; *bioMérieux*, 2020 WL 759546, at *12.

In addition, for the same reasons as stated above, the indemnification clause of the Merger Agreement does not evidence Ferring's subjective intent to infringe the UMN patent. *See* § III.E.1.b, *supra.* Rather, the Merger Agreement demonstrates that Ferring did not believe it

infringed any valid patent claim, PTX-56.27 (§ 3.9(b)), but was cognizant of potential litigation with Finch/UMN and thus included a cost-sharing provision, PTX-56.20 at § 1.16(h).

This is corroborated by former Rebiotix CEO Lee Jones' testimony regarding a March 16, 2018 email between Ferring Pharma and Rebiotix, which provides contemporaneous support showing that Ferring Pharma and Rebiotix both believed that they had freedom to operate. Tr. at 676:16-677:20; TX-3768. Specifically, the email reflects that Rebiotix believed that it did not infringe recently allowed claims from applications related to the UMN patent—including allowed claim 43 of United States Patent Application No. 15/173,134, which, according to Rebiotix, "requires a human fecal extract that is capable of passing through a 0.5 mm sieve." *Compare* TX-3768 at 3 *with* JTX-1 at cl. 4 ("wherein said fecal extract or preparation is capable of passing through a 0.5 mm sieve"). The email states, "Rebiotix has conducted testing of RBX2660 [REBYOTA] and found that this product does contain particles having a size greater than 0.5 mm, actually greater than 0.6mm (600 micron). Because of this, RBX2660 would contain particles that are not capable of passing through a 0.5 mm sieve." TX-3768 at 3. The same email goes on to explain that the properties of the strainer bag make it very different from a sieve. TX-3768 at 3-4. Thus, Ferring did not subjectively believe it was infringing valid claims.

b. Any alleged pre-issuance copying from UMN is not relevant to the willfulness inquiry.

In addition to relying on the Merger Agreement, Finch/UMN attempts to assert willful infringement of the UMN patent on the basis that Rebiotix copied information from UMN. This argument fails as a matter of law. In general, pre-patent-issuance actions are not relevant to willfulness unless they are "particularly egregious" and show a party's subjective intent to infringe. *Bioverativ*, 2020 WL 1332921, at *2 (collecting cases); *see also Gustafson*, 897 F.2d at 510. This makes sense and is particularly relevant here, where the evidence of alleged copying is

from years before the application resulting in the UMN patent was even filed, much less issued.

In the cases where pre-issuance activities have been determinative, the behavior required typically shows a continued and systematic action by the accused infringer—essentially misappropriation, *see, e.g.*, *Chimie v. PPG Indus., Inc.*, 218 F.R.D. 416, 421-22 (D. Del. 2003), or evidence of "a most elaborate and detailed copying" of information pre-issuance, *see, e.g.*, *State Indus.*, 751 F.2d at 1238 (distinguishing the elaborate copying in *Milgo Elec. Corp. v. United Business Communc'ns, Inc.*, 623 F.2d 645 (10th Cir.)). That is not present here. There are no claims for misappropriation, nor any evidence of an elaborate scheme to copy UMN's FMT technology. Finch admitted as much during closing. Tr. at 1153:9-14. On this basis alone the Court can find, as a matter of law, that no reasonable jury would have a legally sufficient evidentiary basis to rely on Finch/UMN's alleged copying evidence to show willfulness.

c. The totality of the evidence shows that Rebiotix did not copy UMN's information in developing REBYOTA.

Further, no reasonable jury, based on the evidence presented at trial, could conclude that Rebiotix copied anything. That evidence primarily concerned Lee Jones's possession of certain information about UMN's FMT program, specifically: (i) the stage gate disclosure form from Drs. Khoruts, Sadowsky, and Hamilton, PTX-419; (ii) a PowerPoint presentation, PTX-42; (iii) UMN's provisional patent application, PTX-422; and (iv) a process protocol, PTX-401. At most, this evidence shows that Lee Jones/Rebiotix was aware of UMN's work and had access to certain information regarding that work—not that it was copied. And knowledge alone is insufficient to support a finding a willfulness. *Bayer*, 989 F.3d at 988.

First, the stage gate document is a business document that provides virtually no technical information to copy, instead providing only a general overview of the alleged invention and little detail on the process itself. PTX-419. The stage gate document notes only that a process to make

a "cleaned", "purified" and "modified" FMT product was developed, PTX-419.5, but that any patent claims are "potentially weak," PTX-419.3. The document also indicates that, in reality, UMN is still actively researching. *See, e.g.*, PTX-419.5 (noting that to date 29 patients had been treated). Finch/UMN adduced no evidence at trial of copying anything from this document.

Second, the PowerPoint presentation is also a business document analyzing the value of the proposed technology, and it provides little information about UMN's process or the FMT product itself. PTX-42.10. The information it does provide, however, indicates that the end goal of UMN's research is a freeze-dried capsule, PTX-42.11, not an enema product like REBYOTA, that would be 99.9% free of non-living fecal material, PTX-42.10. Finch/UMN presented no evidence that Rebiotix copied anything from this business document.

Finally, the provisional patent application, PTX-422, and process protocol, PTX-401, relied on by Finch/UMN include virtually the same information. Notably, the provisional application has claims that are vastly different from those that would issue in the UMN patent. *Compare* PTX-422.20-.21 *with* JTX-1.32-.33. Also, both the provisional application and protocol describe a specific manufacturing process where stool is mixed with phosphate buffered saline in a blender that is purged with nitrogen gas, then passed through a series of sequential sieves (2.0 mm, 1.0 mm, 0.5 mm, and 0.25 mm), then the filtrate from the 0.25 mm sieve is collected in centrifuge tubes and centrifuged, with the supernatant discarded and the resulting pellet that forms during centrifugation being resuspended in 125 mL of saline. PTX-401.1; PTX-422.17 to -.18. As explained below, Finch/UMN presented no evidence that this process was copied and instead, in stark contrast, repeatedly argued that blending, sieving, and centrifugation are not part of the claims. *See, e.g.*, Tr. at 422:8-20 (Benson).

Separately, Finch/UMN relied on two documents at trial, PTX-266 and PTX-268, to

allege that Rebiotix copied the process disclosed in a published UMN paper—Hamilton 2012—in developing the REBYOTA manufacturing process. But the process described in Hamilton 2012 is substantially the same as that described in Example 3 of the provisional application discussed above (and is Example 4 of the UMN patent). PTX-48.3; PTX-422.17 to -.19; JTX-1 at 19:64-29:44 (Ex. 4) Based on the evidence presented at trial, including the testimony of Lee Jones, Courtney Jones, and Dr. Johnson, no reasonable jury could conclude that Rebiotix copied this method. Rather, the evidence adduced at trial demonstrates that the REBYOTA manufacturing process was independently developed and is significantly different from the so-called Hamilton process. Tr. at 654:16-659:21, 684:22-685:9 (L. Jones), 732:10-734:5, 736:13-24 (C. Jones), 793:20-794:25 (Johnson).

The documents relied on by Finch/UMN also highlight the differences between the method used in Hamilton 2012 and that used to manufacture REBYOTA. PTX-268 is a request for proposal ("RFP") from Advanced Bioscience Laboratories regarding FMT process development, and PTX-266 is a response from Rebiotix to that RFP. At trial, Finch/UMN relied on the statement in Rebiotix's response indicating that "[t]he current manufacturing process for RBX2660 is cGMP compliant and was derived from the Hamilton procedure, described in appendix 4 of the RFP . . . ." PTX-266.5. Importantly, however, the sentence continues to say, "and additional landmark papers including Brandt, Borody, van Nood, and Khoruts. These were combined with the process development completed by Rebiotix." PTX-266.5 to -.6. Thus, Hamilton 2012 is one of several seminal papers, all within the public domain, discussing FMT.

Additionally, the RFP response includes a table showing the differences between Hamilton 2012 and the REBYOTA manufacturing process. PTX-266.8. These are the same differences that Finch/UMN's counsel elicited from Lee Jones and Dr. Johnson on cross-

examination during trial, Tr. at 684:22-685:9 (L. Jones), 793:20-794:25 (Johnson), including a different amount of excipient, stomaching rather than vortexing, and the lack of centrifugation and resuspension. PTX-266.8. Regarding PTX-268, the RFP indicates that it actually was Advanced Bioscience Laboratories who requested that the process be "adapted from Hamilton, 2012." PTX-268.15, -.26. However, the development of the Rebiotix process already had been completed two years before Advanced Bioscience Laboratories even made this request, PTX-268.1; Tr. at 738:8-10 (C. Jones), and as explained above, the process was derived independent of any information from UMN.

For the reasons above, Ferring respectfully submits that no reasonable jury would have a legally sufficient basis to conclude that Ferring copied information from UMN to develop the REBYOTA manufacturing process and that such evidence is legally sufficient to support a finding of willfulness as to the UMN patent, and there was certainly no evidence whatsoever that Ferring copied the Borody patents.

F. No reasonable jury could award an upfront payment.

1. There is no substantial evidence that the allegedly novel aspects of the claimed inventions provide value to REBYOTA.

Mr. Malackowski relied on Finch/UMN's other experts to conclude that "the University and Finch patents contribute critically to REBYOTA's composition" and that "they need these patents in order to achieve the sales they hope." Tr. at 480:1-17. However, Finch/UMN's technical experts attributed value only to either unclaimed or non-novel aspects of the asserted claims when describing the value that the patented inventions supposedly provide to REBYOTA. Such testimony is irrelevant to the damages analysis because "[t]he 'value of what was taken'—the value of the use of the patented technology—measures the royalty." *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014) (quoting *Dowagiac Mfg. Co. v. Minn.*

Moline Plow Co., 235 U.S. 641, 648 (1915)). In particular, "where a royalty is at issue, '[n]o matter what the form of the royalty, a patentee must take care to seek only those damages attributable to the infringing features.'" *Omega Patents, LLC v. CalAmp Corp*., 13 F.4th 1361, 1376 (Fed. Cir. 2021) (quoting *VirnetX, Inc. v. Cisco Sys., Inc*., 767 F.3d 1308, 1326 (Fed. Cir. 2014) (noting that a reasonable royalty can take the form of a lump-sum payment or running royalty)); *see also Ericcson, Inc. v. D-Link Sys, Inc*., 773 F.3d 1201, 1226 (Fed. Cir. 2014) ("The essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product."). Thus, "[w]hen a patent covers the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015).

In this case, the "value" of the patented inventions identified by Finch/UMN's technical experts relates to solely conventional elements of the claimed invention rather than the allegedly novel elements thereof. For example, as to the Borody patents, Dr. Benson testified:

> The Finch patents are more about preparing that microbiota sample in a way that allows it to be distributed. So it's about collecting it from donors at central locations. It's about putting cryoprotectants into that microbiome sample or to the stool sample and antioxidants into the stool sample to stabilize it during freezing and to keep -- help keep oxygen away from it. And then transferring that frozen sample to remote facilities. So the sample could be shipped out to healthcare providers where healthcare providers can then administer the samples remotely.

Tr. at 353:20-354:8. But Finch/UMN is not challenging the jury's determination that both claim 21 of the '309 patent and claim 9 of the '080 patent are invalid as obvious. *See* D.I. 496. Thus, each and every benefit of the Borody patents identified by Dr. Benson—including the addition of both cryoprotectants and antioxidants to help stabilize the sample during freezing and help keep

oxygen away from the sample to allow the frozen sample to be shipped to remote facilities—result from conventional elements and cannot be the basis for determining damages attributable to the infringing features. *AstraZeneca v. Apotex*, 782 F.3d at 1338.

The only allegedly novel feature of the invention claimed in claim 16 of the '309 patent is the specific use of PEG as the cryoprotectant, and Mr. Malackowski did not consider the incremental value of using PEG as a cryoprotectant in the claimed invention. Moreover, Mr. Malackowski admitted that he "did not separately appraise the innovations in the Hlavka patents," over which claim 21 of the '309 patent and claim 9 of the '080 patent were found invalid as obvious. Tr. at 514:17-21. Mr. Malackowski also admitted that he did not study the value from the prior art of using a cryoprotectant or antioxidant in FMT, both of which the jury determined were taught by Hlavka. Tr. at 515:2-7. Similarly, the only allegedly novel feature of claim 2 of the '080 patent relates to the "when the sealed container is frozen or exposed to air" limitation, JTX-6 at cl. 2, but neither Mr. Malackowski nor any of Finch/UMN's technical experts testified regarding any alleged value attributable specifically to containers.

Regarding the UMN patent, Dr. Benson testified:

> The '914 patent is really about trying to standardize the approach for preparation of the FMT material. The fecal material that's processed in a blender and was filtered through a series of sieves, and that preparation when prepared that way would contain at least 6 of the 20 or so common classes of bacteria that are typically found in the microbiome of healthy subjects.

Tr. at 352:12-22. He then testified that administering the composition that had been prepared in this "standardize[d]" manner would result in certain outcomes. Tr. at 352:23-353:19. But nothing in claim 7 of the UMN patent requires a specific, standardized manufacturing process. JTX-1 at cl. 4, 7 (requiring only "said fecal extract or preparation is capable of passing through a 0.5 mm sieve"). Also, it is undisputed that the use of FMT is not new or novel, and Mr. Malackowski

does not have the technical knowledge to determine whether "in order to have a commercial product, it would be essential that the product would be capable of passing through a .5 millimeter sieve." Tr. at 512:1-513:1. Because the asserted claim does not require the very thing that Dr. Benson testified resulted in value (the use of a "standardize[d]" process), his testimony cannot be the basis for determining damages attributable to the infringing features.

Notably, Mr. Malackowski also misunderstood or misrepresented Dr. Benson's opinions. Mr. Malackowski testified that in providing opinions regarding the value of the asserted patents, he relied on a purported opinion from Dr. Benson "that in view of Finch's patent portfolio, it would be impossible to develop a product using fecal transplant technology directed to C. diff." Tr. at 511:16-25. But Dr. Benson testified to the opposite, admitting that it would not be impossible to develop a product in this field without using the asserted patents. Tr. at 418:6-16 (further testifying that he did not believe that he had told Mr. Malackowski differently).

Mr. Malackowski failed to assess the relative value of the allegedly novel aspects of the inventions claimed in the patents in suit in comparison to the value of the conventional elements recited therein. Therefore, his opinions—including Mr. Malackowski's opinions regarding an upfront payment—cannot support the award of a reasonable royalty as a matter of law.

2. Mr. Malackowski could not properly apportion damages based on the Seres/Nestle agreement because that agreement does not identify what patents are licensed.

Mr. Malackowski used the Seres/Nestle agreement as the starting point for his opinions regarding a reasonable royalty based on the outcome of the hypothetical negotiation. Tr. at 489:6-13, 503:4-12. As explained in greater detail in the following section, the Seres/Nestle agreement is not a comparable agreement because it is a product collaboration agreement—not a straight patent license agreement—and Mr. Malackowski did not properly account for such differences in his analysis. Thus, it is improper to suggest that the entire $175M upfront payment

in the Seres/Nestle agreement is attributable to intellectual property rights. However, even accepting this faulty assumption, a proper damages analysis requires a comparison of the patent rights conveyed by the Seres/Nestle agreement with those that would be conveyed as a result of the hypothetical negotiation. Although "allegedly comparable licenses may cover more patents than are at issue in the action, include cross-licensing terms, cover foreign intellectual property rights, or [] be calculated as some percentage of the value of a multi-component product[; t]estimony relying on licenses must account for such distinguishing facts when invoking them to value the patented invention." *Ericsson*, 773 F.3d at 1227. Mr. Malackowski failed to account for such differences between the Seres/Nestle agreement and the subject matter of the hypothetical negotiation, which would be a straight patent license to the asserted claims.

In fact, it is impossible to account for such differences, because the version of the Seres/Nestle agreement relied on by Mr. Malackowski does not even indicate what patents are covered by that agreement. Tr. at 519:4-13; *see also* PTX-366.161. Thus, as explained by Ferring's damages expert Mr. Kidder, "the only thing we know is that the patents that were licensed or that were part of that agreement were not the patents in this case." Tr. at 971:14-972:25. As described in the draft press release attached to the agreement, the Seres/Nestle agreement is directed towards "jointly commercializ[ing] SER-109, Seres' investigational oral microbiome therapeutic," which is "comprised of purified Firmicutes spores, based on their modulatory role in the life cycle of *C. difficile* and disease pathogenesis." PTX-366.166. Without a listing of the patents covered by the Seres/Nestle agreement, the subject matter of the included patents is unknown and may include patents directed to things like the isolation and/or purification of the Firmicutes spores, manufacture of the oral formulation, aspects related to oral delivery/bioavailability, methods of treatment related to the use of purified Firmicutes spores, or

any other of a multitude of potential issues that have nothing to do with the asserted claims or REBYOTA. When Dr. Benson was asked whether the Seres/Nestle agreement had any technical aspects in common with a license to the asserted claims, all that he could offer was that "even though the products are different, they're both FMT-type approaches, where fecal microbiota are being transferred and transplanted into individuals with recurrent CDI." Tr. at 401:18-402:5. Even if accepted as true, this does not provide any detail that could be used to properly apportion damages based on the value of the (unknown) patents covered by the Seres/Nestle agreement relative to the asserted claims.

These deficiencies are highlighted by the apportionment methodology that Mr. Malackowski did use. Rather than comparing the value of the technology licensed in the Seres/Nestle agreement to the asserted claims, Mr. Malackowski first suggested that the patents licensed in the Seres/Nestle agreement (which were not identified) accounted for 50% of the value of the $175M upfront payment ($87.5M) and that "know-how" accounted for the other 50% of that payment. Tr. at 503:15-504:18 Notably, the 50/50 split does not even come from the Seres/Nestle agreement but rather was borrowed from other agreements in an apparent attempt to make Mr. Malackowski's litigation position more palatable for the jury. Tr. at 503:15-504:18. Mr. Malackowski then relied on the upfront payment included in the Ferring Pharma/Rebiotix Merger Agreement to suggest he "also took into account what [he] thought would be Ferring's argument of they have their own market benchmark of what they paid for similar technology of 51 million," when he decided to "cut the upfront payment back again to 50 million." Tr. at 504:21-505:6; *see also* Tr. at 500:25-501:19. But as Mr. Kidder explained, the $51.5M upfront payment in the Ferring Pharma/Rebiotix Merger Agreement was "[t]o buy the entire company"—not to license specific patents. Tr. at 966:3-13. Thus, the value of the upfront

payment in that agreement (i) is not tied to or apportioned for any specific intellectual property or patent rights and (ii) has nothing to do with the value of any of the patent rights assigned under the Seres/Nestle agreement. There is no justifiable basis to suggest that the Ferring Pharma/Rebiotix Merger Agreement could be used to apportion damages to account for specific intellectual property rights in a totally unrelated agreement.

Mr. Malackowski's treatment of the Merger Agreement also shows that he improperly considered the hold-up value of the technology rather than the incremental value added to REBYOTA by the claimed inventions. For example, he testified that his opinion was influenced by the fact that Finch would know that supposedly "[t]he other side needs your technology, and now you know that they made already a significant investment knowing they needed that technology." Tr. at 501:22-502:15. Such opinions improperly conflate the value of blocking someone from using a technology with the incremental value added by the claimed invention and show that Mr. Malackowski's damages opinions cannot form the basis of a proper calculation of damages. *Mondis Tech. Ltd v. LG Elecs., Inc*., 407 F. Supp. 3d 482, 494-495 (D.N.J. 2019).

For the reasons above, both steps of Mr. Malackowski's attempt to apportion the value of the upfront payment in the Seres/Nestle agreement suffer foundational defects that fatally undermine his analysis. Even if they did not, Mr. Malackowski's analysis fails to account for the patent rights that were conveyed under the Seres/Nestle agreement. Without this starting point, any attempt to apportion is in vain because it is untethered to the facts of that agreement and this case. Therefore, Mr. Malackowski's opinions regarding an upfront payment cannot support the award of a reasonable royalty as a matter of law.

3. There is no substantial evidence that the Seres/Nestle agreement is sufficiently comparable to serve as the starting point for a hypothetical negotiation.

Both experts agree that "a product license is fundamentally different from a patent

license." Tr. at 923:21-924:2 (Kidder), 520:10-14 (Malackowski). However, Mr. Malackowski's testimony that the Seres/Nestle agreement is "an IP license" rather than a product agreement, *see* Tr. at 489:14-490:4, 490:14-491:1, contradicts the plain language of the agreement and Seres/Nestle's own descriptions of the agreement.

As Mr. Kidder explained, nothing in the Seres/Nestle agreement ties the $175M upfront payment to rights in the (unknown) patents licensed under that agreement. Tr. at 924:12-925:6. Indeed, the agreement itself makes clear that the license grant was to develop, commercialize, conduct medical affairs, and otherwise use the Licensed Products and Collaboration Products:

> Seres hereby grants to Licensee a Co-Exclusive (with Seres and its Affiliates), ***perpetual license*** under the Licensed Intellectual Property, with the right to sublicense (subject to Section 2.2) through multiple tiers, ***to*** (a) Develop, Commercialize, and conduct Medical Affairs Activities in respect of Licensed Products in the Licensed Territory in the Field and to use Licensed Products in connection therewith, and (b) ***Develop, Commercialize, and conduct Medical Affairs Activities in respect of Collaboration Products*** in the Licensed Territory in any field or indication ***and to use Collaboration Products*** in connection therewith.

PTX-366.40. Further, the agreement specifically defines "Collaboration Products" to "mean SER-109 and any improvements and modifications thereto." PTX-366.8. Thus, this is not a bare license to intellectual property rights, but rather a license to develop, commercialize, and conduct medical affairs concerning SER-109, an established product candidate that was close to and subsequently received FDA approval. Tr. at 459:11-460:11.

This is consistent with the rights and obligations throughout the Seres/Nestle agreement, including the Background statement that "Seres is now willing to grant to Licensee, and Licensee desires to obtain, certain co-exclusive rights and licenses ***with respect to the commercialization of SER-109*** in the United States and Canada." PTX-366.2. Similarly, Seres filed a quarterly report with the Securities and Exchange Commission wherein it provided a more readable

summary of the voluminous agreement. Tr. at 925:7-926:8, 973:4-9 (Kidder). It explains:

> The up-front payment of [$175,000,000] compensated the Company for: (i) the co-exclusive license for SER-109 to develop, commercialize and conduct medical affairs in the United States and Canada, (ii) services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of SER-109 in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of SER-109 in the United States. The commercialization activities, which include the commercial manufacturing, participation on joint steering committees and medical affairs work, that occur after regulatory approval of SER-109 in the United States, are part of the 50/50 sharing of commercial profits. Therefore, the up-front payment of $175,000 does not compensate the Company for these activities.

PTX-1733.19. Seres did not suggest the $175M upfront payment was for intellectual property.

Similarly, Finch's chief financial officer Mr. Burgess testified that Finch considered the Seres/Nestle agreement to be a benchmark for licenses related to its patents, and Mr. Malackowski relied on that testimony to support his opinions. Tr. at 438:6-439:15, 491:7-15. But the Finch correspondence that Mr. Burgess relied on recognizes that the Seres/Nestle agreement is an "SER-109 co-commercialization agreement," not an intellectual property license, and purports to give "insight into the value that big pharma might pay for Finch ***products***," not for a license to Finch's patents. PTX-1731.1.

No evidence presented at trial supports Mr. Malackowski's unsupported assumption that the entirety of the $175M upfront payment was compensation for intellectual property, and overwhelming evidence was presented contradicting that opinion. Thus, there is no substantial evidence to support the conclusion that the Seres/Nestle agreement is an intellectual property license rather than a product license.

Mr. Malackowski compounded his error by repeatedly conflating product licenses with patent licenses, despite recognizing that the two are fundamentally different. For example, Mr.

Malackowski admitted that none of the licenses that he considered to be comparable were licenses to patents standing alone. Tr. at 521:1-4. But as explained above, he still suggested, without support, that the entirety of the upfront payment associated with the Seres/Nestle agreement should be attributed to licenses to (unknown) patents and know how.

Additionally, Mr. Burgess testified that Ironwood approached Finch with a proposal for an "exclusive license to develop and commercialize CP101" and "were making an offer to kind of take CP101 onto the market." Tr. at 436:25-437:5. But in explaining the alleged importance of this agreement to the jury, Mr. Malackowski characterized it as a "license [to] their patents" that established a "floor" as to what Finch would accept for a straight patent license:

> That's not a license agreement. That is an offer to license. So it was never executed and carried forward. Ironwood reached out to Finch, offered to license their patents for 25 million upfront, almost a quarter-billion in milestones and up to an 11% royalty. And as we heard Mr. Burgess explain, they turned them down. They said that wasn't economically sufficient and walked away. ***So from my perspective, that's an important consideration because it represents essentially a floor. We know at which point Finch would not agree to a license.***

Tr. at 491:19-492:5. Having recognized that there is a fundamental difference between patent licenses and product licenses, Mr. Malackowski's testimony regarding the Ironwood proposal—indisputably a proposal to license the right to commercialize Finch's patent, not a proposal to license its patents—must be seen as nothing short of a deliberate attempt to confuse the jury by improperly conflating these two types of licenses. And the attempt worked; not coincidentally, the jury awarded an upfront fee of $25M, exactly the amount characterized by Mr. Malackowski as the "floor" acceptable to Finch.

For the reasons provided above, Mr. Malackowski's opinions cannot provide a basis to award an upfront payment as a matter of law. Moreover, Mr. Kidder testified that Ferring would not have been willing to pay an upfront payment as part of a reasonable royalty in this situation.

Tr. at 921:5-8. Therefore, the Court should vacate the jury's award of a $25M upfront payment.

G. The jury's award of a $25M upfront payment is unsupported and excessive.

If the Court does not vacate the jury's award of an upfront payment outright, Ferring respectfully requests remittitur of the upfront payment award. Even if the Court finds that an upfront payment cannot be excluded as a proper remedy here as a matter of law, remittitur is appropriate where the Court determines that the damages award is "intrinsically excessive in the sense of being greater than the amount a reasonable jury could have awarded, although the surplus cannot be ascribed to a particular quantifiable error." *Boyce v. Edis Co*., 224 F. Supp. 2d 814, 817 (D. Del. 2002). And because "the record is wholly lacking in evidence that would allow the Court to determine the value of a reasonable royalty" as it relates to such a payment, the Court should remit the jury's award of an upfront payment to no or nominal damages. *Rex Med. v. Intuitive Surgical, Inc*., No. 19-005-MN, 2023 WL 6142254, at *11 (D. Del. Sept. 20, 2023).

H. If the Court finds either the Borody patents or the UMN patent invalid or not infringed, then damages should be reduced.

Where "the jury rendered a single verdict on damages, without breaking down the damages attributable to each patent, the normal rule would require a new trial as to damages." *Verizon Servs. Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1310 (Fed. Cir. 2007). However, a new trial is not required if a reasonable jury could have determined the damages award omitting the error. *See WesternGeco L.L.C. v. ION Geophysical Corp*., 913 F.3d 1067, 1074 (Fed. Cir. 2019). Here, even if the Court grants any of the currently pending motions regarding non-infringement or invalidity of the Borody patents or the UMN patent, a new trial is not needed because the experts agreed that the Borody patents and UMN patent were "roughly equal in contribution." Tr. at 506:10-507:1, 934:19-935:4.

Mr. Malackowski's alternative opinion that Finch/UMN should be awarded the entire

damages amount if even a single claim of any patent is found valid and infringed, Tr. at 507:4-9, is contrary to the law. It cannot be true that two groups of patents are equally important to an accused product but also that a license to either would require payment of the full amount of the requested royalty, as such an opinion fails to account for the incremental value of the individual patented inventions as separate inventions. *Omega*, 13 F.4th at 1376; *Mondis*, 407 F. Supp. 3d at 492 ("Mondis built its damages case on evidence of previous licenses which were all structured on a threshold basis. . . . Mondis now claims that, also, these threshold licenses built in apportionment, but this is paradoxical: a license which is designed so that the underlying patents have no incremental value cannot at the same time be evidence of the incremental value that the patented invention adds to the end product.") (internal quotations omitted). Therefore, to the extent that the Court adjudges either of the Borody patents or the UMN patent not infringed or invalid, then the damages award should be proportionally reduced. Tr. at 506:10-507:1.

IV. CONCLUSION

For the reasons set forth above, Ferring respectfully requests that the Court grant JMOL in favor of Ferring on all six grounds.

Dated: September 26, 2024

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